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Shanghai Henlius Biotech, Inc.

上海復宏漢霖生物技術股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock code: 2696)

VOLUNTARY ANNOUNCEMENT

THE INVESTIGATIONAL NEW DRUG APPLICATION FOR CLINICAL TRIAL OF HLX43 FOR INJECTION (AN ANTIBODY-DRUG CONJUGATE TARGETING PD-L1) IN COMBINATION WITH BEVACIZUMAB WITH OR WITHOUT CHEMOTHERAPY FOR THE TREATMENT OF ADVANCED/METASTATIC SOLID TUMOURS HAS BEEN APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the “**Company**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Company.

The board of directors of the Company (the “**Board**”) is pleased to announce that recently, the investigational new drug application for clinical trial of HLX43 for injection (an antibody-drug conjugate targeting PD-L1) (“**HLX43**”) in combination with bevacizumab with or without chemotherapy for the treatment of advanced/metastatic solid tumours has been approved by the National Medical Products Administration. The Company proposes to commence relevant clinical trials in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, the same as below) when the conditions are fulfilled.

B. ABOUT HLX43

HLX43 is an antibody-drug conjugate (ADC) targeting PD-L1 developed by the Company through conjugating the licensed-in novel DNA topoisomerase I inhibitor small molecule payload – peptide linker, with antibody targeting PD-L1 independently developed by the Company, which is designed for the treatment of advanced/metastatic solid tumours. As of the date of this announcement, the relevant development progress of HLX43 was as follows:

Product/Combination therapy	Indications	Latest progress
HLX43	Advanced/Metastatic solid tumours	Phase 1 clinical trial in Chinese Mainland Thymic carcinoma (TC) cohort as international multicentre trial, Phase 1 clinical trial in Japan and the United States
HLX43	Advanced non-small cell lung cancer (NSCLC)	Phase 2 clinical trial in Chinese Mainland, the United States, Australia, Japan and the European Union countries (international multicentre trial)
HLX43 monotherapy or combination therapy	Advanced/Metastatic solid tumours	Phase 2 clinical trials for metastatic colorectal cancer (mCRC), cervical cancer (CC), esophageal squamous cell carcinoma (ESCC) and other indications in Chinese Mainland
HLX43+HANSIZHUANG	Advanced/Metastatic solid tumours	Phase 1b/2 clinical trial in Chinese Mainland
HLX43+HLX07	Advanced/Metastatic solid tumours	HLX43 in combination with HLX07 or HANSIZHUANG in phase 1b/2 clinical trial for the treatment of advanced/metastatic colorectal cancer (CRC) in Chinese Mainland HLX43 as monotherapy or in combination with HLX07 in phase 2/3 clinical trial for the treatment of advanced/metastatic squamous non-small cell lung cancer (NSCLC) in Chinese Mainland (international multicentre trial)
HLX43+HLX07+ HANSIZHUANG	Advanced solid tumours	Permitted to commence phase 1b/2 clinical trial in Chinese Mainland
HLX37 in combination with chemotherapy or HLX43	Advanced/Metastatic solid tumours	Permitted to commence phase 1 clinical trial in Chinese Mainland
HLX43+bevacizumab	Advanced/Metastatic solid tumours	Permitted to commence clinical trial in Chinese Mainland

The key subgroup data of HLX43 in the treatment of non-small cell lung cancer (NSCLC) were presented orally at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting. The presentation was based on a pooled analysis of NSCLC patients enrolled in the first-in-human Phase 1 study (HLX43-FIH101) and the global multicentre Phase 2 study (HLX43-NSCLC201), incorporating overseas patient data for the first time. Key efficacy endpoints were assessed by a Blinded Independent Central Review (BICR), and progression-free survival (PFS) data were disclosed for the first time. As of February 28, 2026, a total of 205 patients with advanced NSCLC had been enrolled in the study. Prior platinum-based chemotherapy had been administered in 99.0% of patients, while 82.0% had received prior immunotherapy, 41.0% had received targeted therapy, and 24.4% had previously been treated with docetaxel. Nearly 40% of patients had received three or

more prior lines of therapy. In addition, 27.8% of patients had bone metastases, 13.7% of patients had brain metastases, and 13.7% had liver metastases. The study population thus represented a heavily pretreated cohort with a substantial disease burden. Among patients with EGFR wild-type nonsquamous NSCLC (nsNSCLC), treated with HLX43 monotherapy at 2.5 mg/kg (n=19), the confirmed objective response rate (cORR) was 36.8%, the confirmed disease control rate (cDCR) was 94.7%, and the median progression-free survival (mPFS) was 6.67 months. In patients with squamous NSCLC (sqNSCLC) who had previously failed docetaxel treatment (2mg/kg, n=33), cORR and mPFS reached 33.3% and 6.34 months, respectively; and in patients with sqNSCLC who had previously failed docetaxel treatment and received third-line or later therapy (2mg/kg, n=15), HLX43 monotherapy achieved a cORR of 46.7%, a cDCR of 80.0%, and an mPFS of 6.90 months. These results compare favourably with historically reported response rates for conventional chemotherapy (docetaxel) in this population. Among patients with PD-L1-positive tumours (TPS $\geq$ 1%, n=29) and those with PD-L1-negative or unevaluable tumours (TPS <1% or NE, n=39), the cORRs were 37.9% and 33.3%, respectively, while the cDCRs reached 89.7% and 84.6%, respectively, with no meaningful difference observed between the two groups. Notably, the mPFS in the PD-L1-positive subgroup reached 6.80 months, and 5.49 months in the PD-L1-negative group. These findings suggest that HLX43 may provide clinical benefit regardless of PD-L1 expression status. Regarding safety and tolerability, HLX43 demonstrated a consistent and favourable safety profile across the 205-patient analysis population encompassing multiple dose levels, NSCLC subtypes, and treatment backgrounds.

C. MARKET CONDITION

As of the date of this announcement, no similar combination regimen has been approved for marketing globally.

WARNING STATEMENT WITH REFERENCE TO THE REQUIREMENTS UNDER RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED: The Company cannot guarantee the successful development and commercialisation of HLX43. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 31 July 2026

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and non-executive director, Dr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yuqing Chen, Ms. Xiaohui Guan, Dr. Yi Liu and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Ruilin Song and Mr. Yihao Zhang as the independent non-executive directors.